



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0563]

Single-Ingredient, Immediate-Release Drug Products Containing Oxycodone for Oral

Administration and Labeled for Human Use; Enforcement Action Dates; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the Federal Register of July 6, 2012 (77 FR 40069). The document announced FDA's intention to take enforcement action against all unapproved single-ingredient, immediate-release drug products that contain oxycodone hydrochloride for oral administration and are labeled for human use, and persons who manufacture or cause the manufacture or distribution of such products in interstate commerce. The document was published with an incorrect Web link. This document corrects that error.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: In FR Doc. 2012-16475, appearing on page 40069 in the Federal Register of Friday, July 06, 2012, the following correction is made:

1. On page 40070, in the first column, in the last paragraph, the Web link “<http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/SelectedEnforcementActionsonUnapprovedDrugs/ucm238675.htm>)” is corrected to read “<http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/SelectedEnforcementActionsonUnapprovedDrugs/ucm238675.htm#narcotics>)”.

Dated: July 9, 2012.

Leslie Kux,

Assistant Commissioner for Policy.